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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,327	10/03/2005	Akio Inui	480.1001	7240

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EXAMINER	
DANG, IAN D	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
07/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,327	INUI ET AL.	
	Examiner	Art Unit	
	Ian Dang	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4 and 7-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4 and 7-9* is/are rejected.

7)☒ Claim(s) *4 and 7-9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/02/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *PTO-90C and revised notice*.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II, claims 4 and 7-9 in the communication filed on 05/14/2007 is acknowledged. Claims 1-3 and 5-6 have been cancelled. Claims 4 and 7-9 are pending and under examination.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825). See sequence compliance letter attached to the instant Office Action.

Claim Objections

Claims 4 and 7-9 are objected to because of the following informalities:

Claims 4 and 7-9 use the acronym GHS-R without first defining what it represents in the independent claims. While the claims can reference acronyms, the material presented by the acronym must be clearly set forth at the first use of the acronym.

Appropriate correction is required.

Claim Rejections - 35 USC § 112 (Written Description)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4 and 7-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 4 is drawn to a method of lowering the blood glucose level by administering a GHS-R antagonist. Claim 7 is drawn to a method of preventing or treating diabetes mellitus, which comprises administering an effective dose of GHS-R antagonist. Claim 8 is drawn to a method of preventing or treating obesity which comprises administering an effective dose of GHS-R antagonist, claim 9 is drawn to a method of suppressing appetite which comprises administering an effective dose of GHS-R antagonist. Specifically, the specification teaches that the GHS-R antagonists, which are used as active ingredients in the present invention, are substances that can bind to GHS-R, thereby inhibiting the effects of the agonists (page 8, lines 13-15).

Thus, the claims are genus claims. The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Specifically, the specification does not clearly define GHS-R antagonist and all methods of using such. Thus, the scope of the claims includes numerous structural and functional variants, and the genus' are highly variant because a significant number of structural and functional differences between genus members is permitted. The specification and claims do not provide any guidance as to what changes should be made. Structural and functional features that could distinguish GHS-R antagonist are missing from the disclosure. No common attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted

description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, GHS-R antagonist is insufficient to describe the genus.

The written description requirement for a claimed genus' may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and function structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. In the instant case, the specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the genus for GHS-R antagonist and all methods of using such.

There is no description of the special features, which are critical to the structure and function of the genus claimed. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify GHS-R antagonist encompassed by the limitations. Thus, no identifying characteristics or properties of the instant GHS-R antagonist is provided such that one of skill would be able to predictably identify the encompassed variant biological and chemical entities recited in the methods of the instant claims. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Claim Rejections - 35 USC § 112 (Enablement)

Claims 4 and 7-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for (1) a method for reducing food intake comprising administering the GHS-R antagonist [D-lys-3]-GHRP-6 or [D-Arg-1, D-Phe-5, D-Trp-7, 9 Leu-11] substance P and (2) a method for lowering the blood glucose level comprising administering [D-Lys-3]-GHRP-6, (3) a method for treating diabetes mellitus comprising administering [D-Lys-3]-GHRP-6, and (4) a method for treating obesity comprising administering [D-Lys-3]-GHRP-6, a method of suppressing appetite comprising administering [D-Lys-3]-GHRP-6, does not reasonably provide enablement for (1) a method of lowering the blood glucose level by administering a GHS-R antagonist, (2) a method of preventing or treating diabetes mellitus which comprises administering an effective dose of GHS-R antagonist, (3) a method of preventing or treating obesity which comprises administering an effective dose of GHS-R antagonist, (4) a method of suppressing appetite which comprises administering an effective dose of GHS-R antagonist. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include: (1) Nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the breath of the claims, (7) the quantity of experimentation needed, (8) relative skill of those in the art.

Nature of the invention and breath of the claims

The invention is drawn to methods of treatment by administering a GHS-R antagonist. The invention is broad because the recitation of claims 4 and 7-9 encompasses a large number of antagonists. The recitations of claims 4 and 7-9 comprise any substances binding to the receptor and each substance has distinct structure and biological activity. The teachings in the specification provide general characteristics of these antagonists but the specification does not provide any distinguishing or specific characteristics for any of these antagonists required for a method of treatment. For instance, the specification teaches that the GHS-R antagonists which are used as active ingredients in the present invention are substances that can bind to GHS-R, thereby inhibiting the effects of the agonists (page 8, lines 13-15).

Unpredictability and state of the art

The state of the art for reducing food intake in mice or rats administering with the ghrelin antagonist [D-Lys3]-GHRP is well known, but the state of the art for any antagonist of GHS-R as a therapeutic for lowering blood glucose, treating diabetes mellitus, an obesity is not well characterized presently.

The antagonist [D-Lys3]-GHRP has been shown to reverse hyperphagia and limit the intake of food in rats and mice. For instance, Ishii et al., (2002) teach that hyperphagia a feature of an uncontrolled diabetes was reversed by an the ghrelin-receptor antagonist (page 4934, abstract) and food intake at day 14 was significantly decreased in [D-Lys-3]-GHRP-6 treated diabetic rats than saline-treated diabetic rats (page 4936, left column, last paragraph).

In addition, Dong et al. (2006) teach that the attenuation of hyperphagia in ghrelin-/- mice and the reduced food intake during treatment with ghrelin receptor antagonist suggest that

ghrelin should be considered the underlying trigger of hyperhagia associated with uncontrolled diabetes (page 2641, left column, last paragraph).

The GHS-R antagonists claimed in the instant application include compounds with different structure and activities. More specifically, the specification teaches that the GHS-R antagonists, which are used as active ingredients in the present invention, are substances that can bind to GHS-R, thereby inhibiting the effects of the agonists (page 8, lines 13-15).One skilled in the art would not be able to predict that all GHS-R antagonists have the desired function *in vivo* as required by the instant claims.

In addition, one skilled in the art would not be able to predict that all possible GHS-R antagonists can treat or prevent diabetes mellitus or obesity. It is noted that the term "preventing" has been interpreted by the Examiner as meaning that an activity will not occur, i.e. diabetes mellitus and obesity will not occur. However, the specification does not disclose complete prevention of diabetes mellitus and obesity and undue experimentation would be required of the skilled artisan to determine the quantity of GHS-R antagonist to be administered, the best route of administration, the duration of treatment in order to prevent diabetes mellitus and obesity in a patient.

Furthermore, the specification and the claims have not provided sufficient evidence for identifying the patient population needed for a method of lowering blood glucose level and a method of suppressing appetite. The patient population is not well defined for the claimed invention because it includes any patient.

In view of the teachings in the art and the limited guidance provided in the specification for (1) a method for reducing food intake comprising administering the GHS-R antagonist [D-lys-3]-GHRP-6 or [D-Arg-1, D-Phe-5, D-Trp-7, 9 Leu-11] substance P and (2) a method for lowering the blood glucose level comprising administering [D-Lys-3]-GHRP-6, (3) a method for treating

diabetes mellitus comprising administering [D-Lys-3]-GHRP-6, and (4) a method for treating obesity comprising administering [D-Lys-3]-GHRP-6, a method of suppressing appetite comprising administering [D-Lys-3]-GHRP-6 , one skilled in the art would not be able to predict (1) a method of lowering the blood glucose level by administering all possible GHS-R antagonists, (2) a method of preventing or treating diabetes mellitus which comprises administering an effective dose of all possible GHS-R antagonists, (3) a method of preventing or treating obesity which comprises administering an effective dose of all possible GHS-R antagonists, (4) a method of suppressing appetite which comprises administering an effective dose of all possible GHS-R antagonists.

The amount of direction or guidance present

Applicants' disclosure is limited to the administration of the GHS-R antagonists [D-lya-3]-GHRP-6 and [D-Arg-1, D-Phe-5, D-Trp-7, 9 Leu-11] substance P to mice (Figures 10-14). However, the specification does not provide guidance or direction regarding (1) a method of lowering the blood glucose level by administering all possible GHS-R antagonist, (2) a method of preventing or treating diabetes mellitus which comprises administering an effective dose of all possible GHS-R antagonist, (3) a method of preventing or treating obesity which comprises administering an effective dose of all possible GHS-R antagonists, (4) a method of suppressing appetite which comprises administering an effective dose of all possible GHS-R antagonists.

In addition, the specification does not provide guidance regarding the identifying characteristics for the patient population in need of the GHS-R that require treatment for lowering of the blood glucose and for suppressing appetite. The specification only teaches the patient population needed treatment for diabetes mellitus (page 1 line 25 to page 2 line 18) and for obesity (page 2 lines 19-28) but does not disclose any other patient population.

Working Examples

Although Applicants have provided an examples of administering administration of the GHS-R antagonists [D-lya-3]-GHRP-6 and [D-Arg-1, D-Phe-5, D-Trp-7, 9 Leu-11] substance P to mice (Figures 10-14) for effects on food intake in mice (Figures 10-12) and body weight gain in mice (Figure 13) and free fatty acids in mice (Figure 14), the specification does not provide any methods or working examples for the prevention of diabetes mellitus or obesity comprising administering an effective dose for any GHS-R antagonists.

As discussed above, the term "preventing" has been interpreted by the Examiner as meaning that an activity will not occur, i.e. diabetes mellitus and obesity will not occur. The specification also does not provide any methods or working examples for the treatment obesity or diabetes with any GHS-R antagonists.

The quantity of experimentation needed

Without sufficient disclosure in the specification, it would require undue experimentation for one of skill in the art to be able to lower blood glucose level, prevent or treat diabetes mellitus, prevent or treat obesity, and suppress appetite with all possible GHS-R antagonists. In addition, it would require undue experimentation to practice the invention commensurate in scope with the claims because, the claims are broadly drawn to (1) a method of lowering the blood glucose level by administering a GHS-R antagonist, (2) a method of preventing or treating diabetes mellitus which comprises administering an effective dose of GHS-R antagonist, (3) a method of preventing or treating obesity which comprises administering an effective dose of GHS-R antagonist, (4) a method of suppressing appetite which comprises administering an effective dose of GHS-R antagonist.

Claim Rejections - 35 USC § 112 (Second Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 7-9 are indefinite because the claims do not have a step that clearly relates back to the preamble of claims 4 and 7-9. For example, there is no step indicating how the lowering of blood glucose has taken place or how it is measured.

Claim 4 is indefinite because it does not recite any transition phrases defining the scope of the claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim (MPEP 2111.03).

The metes and bounds of the claims cannot be determined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Andersen et al. (US 2001/0020012 A1, published September 6, 2001, filed January 29, 2001).

Andersen et al. teach a method for treatment or prevention of (page 2, paragraph [0022]) Type II diabetes (page 1, paragraph [0013]) with the antagonist for the receptor GHS-R 1A (page 2, paragraph [0022]) meeting the limitations of claim 7.

Although the reference is silent upon lowering blood glucose, the administration of a compound for the treatment of diabetes would inherently result in lowering blood glucose level, as required by the claim 4. For example, it is well known in the prior art that diabetes mellitus is associated with continuous and pathologically elevated blood glucose concentration (Chatterrji et al. (US Patent 6,949,261; column 1, lines 48-49).

In addition, Andersen et al. teach a method for treatment of or prevention (page 2, paragraph [0022]) of obesity (page 1, paragraph [0011]) with the antagonist for the receptor GHS-R 1A (page 2, paragraph [0022]), meeting the limitations of claim 8.

Finally, Andersen et al. teach a method for treatment of or prevention (page 2, paragraph [0022]) for regulation of food intake with the antagonist for the receptor GHS-R 1A (page 6, claims 6 and 8) meeting the limitations of claim 9.

Conclusion

No claim is allowed.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ian Dang whose telephone number is (571) 272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang
Patent Examiner
Art Unit 1647
June 19, 2007

Bridget E. Bunner

BRIDGET BUNNER
PATENT EXAMINER

UNITED STATES DEPARTMENT OF COMMERCE
U.S. Patent and Trademark Office
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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10/520,327	10/03/2005	INUI, Akio	480.1001

EXAMINER	
Ian Dang	
ART UNIT	PAPER
1647	20070613

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

In the specification, Figure 1 does not refer to any sequence identifiers for the sequences disclosed in the figure. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

APPLICANT IS GIVEN THREE MONTHS FROM THE DATE OF THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.F.R.. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ian Dang whose telephone number is (571) 272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bridget E. Bunner

BRIDGET BUNNER
PATENT EXAMINER

Notice to Comply	Application No. 10/520,327	Applicant(s) INUI ET AL.	
	Examiner Ian Dang	Art Unit 1647	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e). The correct SEQ ID NO:2 is present in the paper copy of the of the sequence listing only. Therefore a search of the correct sequence is not possible.

☒ 7. Other: Figure 1 does not refer to any sequence identifiers for the sequences disclosed in the figure.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
For CRF Submission Help, call (703) 308-4212 or 308-2923
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